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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,985	02/03/2004	Nancy J. Harper	PC10139B	3565

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EXAMINER	
OH, TAYLOR V.	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/771,985	Applicant(s) HARPER ET AL.	
	Examiner Taylor Victor Oh	Art Unit 1625	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 February 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: 1-13.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: SEE PAGES 2-8.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

It is noted that applicants have filed an Amendment after the Final Rejection on 2/22/05; applicants' attorney has addressed the issues of record. The proposed amendment will be entered ;however, it is not in a condition for allowance.

The Status of Claims

Claims 1-13 are pending.

Claims 1-13 have been rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of Claims 1-13 under 35 U.S.C. 103(a) as being unpatentable over Doogan et al (U.S. 4,962,128) in view of Howard et al (U.S. 5,597,826) is maintained for the reasons of the record on 8/10/04.

Applicants' attorney has addressed the issues of record; however, has not rebutted the claim rejections ***1-13*** under 35 USC 103 (a).

Applicants' Argument

2. Applicants argue the following issues:

1. The Doogan's recital of " --flavoring agents, coloring matter--", "emulsifying and/or suspending agents, together with diluents--" is within the context of diluents used with a liquid preparation wherein the liquid is mainly water and the resulting preparation is an emulsion or a suspension , not a solution as recited by instant claim 1 ;

2. Howard do not refer to pharmaceutical preparations in which the sole active ingredient is sertraline or its salt, but compositions containing (a) 5-HT reuptake inhibitors and (b) an unspecified compound from Howard' formula I; there is no suggestion in Howard that the compound of Howard' formula I is absent from any preparation recited therein ; there is no indication in Howard that any of the means taught will produce " an essentially non-aqueous ,liquid concentrate solution for oral administration; and there is no recital in Howard that the non-aqueous vehicles form a solution with sertraline alone or pharmaceutically acceptable salts of sertraline alone as opposed to an emulsion or suspension;

3. There is no motivation for the skilled artisan in the art to rely on the teachings of Doogan in the search for " an essentially non-aqueous liquid concentrate solution" ;

4. Applicants' non-aqueous liquid concentrate for oral administration having unique amount and combination of excipients do not suggest in the prior art; and

5. Applicants has responded to the examiner's previous arguments;

6. There is no motivation whatsoever for the combination of Doogan and Howard as Howard refers to methanesulfonate only with respect to the genus of compounds of formula I and Doogan never specifically recites sertraline hydrochloride in any liquid preparation.

Applicants' arguments have been noted, but the arguments are not persuasive.

First, regarding the first argument, the Examiner has noted applicants' argument. However, according to the definition of " a solution " in the Remington's Pharmaceutical Sciences (18^{th} ed. Page 1523), it says that "a solution is a liquid preparation that contains one or more soluble chemical substances dissolved in water "; also, the specification of the current invention has pointed out that the phrase "essentially nonaqueous " refers to the amount of water, "about 10 %", (see page 6 ,line 2) which is present in the final drug product (see page 5 ,lines 32-33). Therefore, on the contrary to applicants'arguments, from the above passages, it becomes obvious that the Doogan's et al oral administration in the form of aqueous suspensions and /or elixirs does encompass the claimed solution. Therefore, applicants' arguments are irrelevant to the issues.

Second, regarding the second and third arguments, the Examiner has noted applicants' argument. However, the secondary Howard et al reference has been used to supplement the primary reference with respect to liquid preparations containing sertraline which may be prepared by conventional means with pharmaceutically acceptable additives such as non-

aqueous vehicles (see col. 22 ,lines 47-55). Furthermore, the Howard et al has indicated that sertraline hydrochloride or methanesulfonate (see col. 20 lines 57-62) useful to treat anxiety-related disorders which can be a part of the pharmaceutical composition, whereas the Doogan et al does teach the pharmaceutical composition containing setraline or its pharmaceutically acceptable salt, flavoring agents, and diluents ,such as ethanol, glycerin and various like combinations thereof , which is also useful in the treatment of anxiety-related disorders. Both prior art are commonly related to the treatment of mood disorders ,such as anxiety disorder, phobias, and etc by using the same setraline compound . Therefore, there is a motivation to combine both prior art. Also, it is well-known in the art that many liquid preparations of conventional means with pharmaceutically acceptable additives are available depending upon the demands of the consumers' market. Therefore, if the skillful artisan in the art had desired to develop the product containing non-aqueous liquid concentrate compositions of sertraline for oral administration, it would have been obvious for the skillful artisan in the art to have been motivated to incorporate Howard et al 's non-aqueous vehicles into the Doogan et al method. This is because the skilled artisan in the art would expect such a combination to be successful as the guidance (see col. 22 ,lines 47-55) shown in the Howard et al which indicates that non-aqueous vehicles can be incorporated in the liquid preparations containing sertraline .

Third, with respect to the fourth argument, the Examiner has noted applicants' argument. However, on the contrary to applicants'arguments, the Doogan et al does teach that oral pharmaceutical formulations can be flavored by means of various agents ; the composition contains sertraline with concentration levels ranging from 0.5 % to 90 % by weight of the total

compositions (see col. 2 ,lines 45-46) or its pharmaceutically acceptable salt, flavoring agents, and diluents such as ethanol, propylene glycol, and glycerin (see from col. 2 line 65 to col. 3, line 2). From this teaching , it is quite possible to make the concentrate form of sertraline as the pharmaceutical composition. Therefore, applicants' arguments are irrelevant.

Third, concerning the fifth argument, the Examiner has noted applicants' arguments. However, in response to applicants' arguments , the examiner has already presented them in the final rejection (see the final office action dated on 11/16/2004). Therefore, applicants' arguments are irrelevant.

Fourth, regarding the sixth argument, the Examiner has noted applicants' argument. However, on the contrary to applicants'arguments, the Howard et al has indicated that the genus of compounds of Howard's et al formula I can be unrelated to sertraline hydrochloride or methanesulfonate (see col. 20 lines 57-62). Also, the Howard et al has disclosed either sertraline hydrochloride or methanesulfonate (see col. 20 lines 57-62) as a part of the pharmaceutical composition to be used in the treatment of anxiety-related disorders(see col. 20 lines 33-34), whereas the Doogan et al does teach generally the pharmaceutical composition which contains setraline or its pharmaceutically acceptable salt, such as hydrochloric acid (see col. 1 , lines 66-68) , flavoring agents, and diluents ,such as ethanol, glycerin and various like combinations thereof; this also can be applied for oral pharmaceutical formulations as aqueous suspensions and/or elixers (see col. 2 , lines 63-64) useful in the treatment of anxiety-related disorders. Therefore, there is a motivation to combine the references. Both prior art references

do describe that the pharmaceutical composition containing sertraline hydrochloride may be combined with various pharmaceutically acceptable inert carrier in the form of syrups and solutions. Also, the Howard et al reference has offered guidance that it is possible to use either hydrochloride or methanesulfonate (see col. 20, lines 60-61) as a pharmaceutically acceptable acid addition salt. Therefore, if the skillful artisan had desired to develop the product containing non-aqueous liquid concentrate compositions containing sertraline or methanesulfonate as pharmaceutically acceptable acid addition salt for oral administration , it would have been obvious to the skillful artisan in the art to have been motivated to use Howard et al 's methanesulfonate into the Doogan et al pharmaceutical composition containing sertraline hydrochloride because, for oral administration, the Howard et al which indicates that non-aqueous vehicles can be incorporated in the liquid preparations containing sertraline . Therefore, there is the motivation to combine the references rejection references to achieve the non-aqueous liquid concentrate having the unique amounts and combination of excipients by routine experimentations.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*** 3/17/05

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